SECTION 2. SUMMARY AND CERTIFICATION

A. 510(K) SUMMARY

Summary of Safety and Effectiveness

In accordance with 21 CFR 807.92, the following information constitutes the Artimplant AB's summary for the Artelon™ Surgical Suture

SUBMITTER'S NAME:	Artimplant AB
ADDRESS:	Hulda Mellgrens gata 5, SE-421 32 Västra Frölunda, Sweden
CONTACT PERSON:	Britt Novén
TELEPHONE NUMBER:	+46 31 7465600 or +46 705 280255
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DATE OF SUBMISSION:	July 11, 2003

1. **Identification of device**
   Proprietary Name: Artelon™ Surgical Suture
   Common Name: Nonabsorbable Nylon Surgical Suture
   Classification Status: Class II per regulations §878.5020
   Product Codes: GAR- Surgical, Nonabsorbable, Synthetic, Polyamide

2. **Equivalent devices**
   Artimplant AB believes the Artelon™ Surgical Suture is substantially equivalent to:

K993998	T.CAD International – Nylon
K981582	Sherwood-Davis & Geck – Surgilon®, Ophtalon® and Dermalon® Non-absorbable Surgical Suture
K003000	Grams American Suture, Inc. – Grams Nylon Nonabsorbable Suture
K001173	C.P. Medical – Nylon Nonabsorbable Surgical Sutures

3. **Description of the Device**
   Artelon™ Surgical Suture is a nonabsorbable braided surgical suture, which is supplied sterile. It is composed of Artelon™, a polycaprolactone based poly(urethane urea), in multifilament form. The Artelon™ Surgical Suture will be offered uncoated and undyed and without needle.

   The product meets all requirements established by the United States Pharmacopoeia (U.S.P) for nonabsorbable surgical sutures.

4. Intended use

The Artimplant, Artelon™ Surgical Suture is intended for use in general soft tissue approximation and/or ligation.

5. Technological characteristics, comparison to predicate device.

Like the predicate devices, the Artelon™ Surgical Suture is intended for general soft tissue approximation and/or ligation.

Company	T.CAD	Sherwood-Davis & Geck	Grams American Suture, Inc.	C.P. Medical	Artimplant AB
Device	International – Nylon	Surgilon®, Ophtalon® and Dermalon® Non-absorbable Surgical Suture	Grams Nylon Nonabsorbable Suture	Nylon Nonabsorbable Surgical Sutures	Artelon™ Surgical Suture
510(k) Number	**K993998**	**K981582**	**K003000**	**K001173**	**No number yet**
Characteristic					
Intended use	General soft tissue approximation and/or ligation Including use in cardiovascular ophthalmic and neurological procedures.	General soft tissue approximation and/or ligation Including use in cardiovascular ophthalmic and neural tissue.	General soft tissue approximation and/or ligation Including use in cardiovascular ophthalmic and neurological procedures.	General soft tissue approximation and/or ligation Including use in cardiovascular ophthalmic and neurological procedures.	General soft tissue approximation and/or ligation
Suture Material	Nylon 6 or Nylon 6,6	Nylon 6 or Nylon 6,6	Nylon 6 or Nylon 6,6	Nylon 6 or Nylon 6,6	Polycaprolactone based poly(urethane urea)
Suture Characteristics	Not absorbed, progressive degradation of the Nylon *in vivo* may result in gradual loss of all of the suture's tensile strength over time	Not absorbed, progressive hydrolysis of the Nylon *in vivo* may result in gradual loss of all of the suture's tensile strength over time	Unknown	Unknown	Not absorbed, progressive degradation by hydrolysis of the poly(urethane urea) *in vivo* will result in gradual loss of all of the suture's tensile strength over time
Suture Diameter	Meet U.S.P. Requirements	Unknown	U.S.P. 24 for diameter 861	U.S.P. 24 for diameter 861	U.S.P. 26 for diameter 861
How supplied	Monofilament thread, coated or uncoated, undyed or dyed with an FDA listed color additive. Sterile and offered for Single Use Only. Available with or without surgical needle.	Braided and monofilament sutures available in various lengths and diameters with or without surgical needles.	Sterile, flexible, monofilament thread or braided thread, dyed or undyed, offered in a variety of lengths and a range of diameters with or without needle.	Monofilament or braided, coated with silicone, or wax, or uncoated, dyed black or dyed blue or undyed white.	Braided, uncoated, undyed without surgical needle.
Packaging	Dry packaged in Aluminum Foil and Polyester tear open packaging	Tyvek/Mylar packaging	Unknown	Unknown	Double peel open laminated aluminium-plastic foil, respectively coated paper and polyester/polyethylene film.

6. Discussion of performance testing.

A collection of tests has been conducted and successfully completed including biocompatibility safety studies, diameter, tensile strength and properties such as pliability and handling in accordance to:

- ISO 10993 standards
- USP 26
- Guidance for surgical suture issued on: August 10, 2000
- Class II Special Control Guidance, Surgical Suture; Guidance for Industry and FDA, June 3, 2003

7. Conclusion

Based on extensive performance testing and a comparison to the predicate devices, we believe that the Artelon™ Surgical Suture is substantially equivalent to devices already on the market (cleared by the 510(k) process) and presents no new concerns about safety and effectiveness. Additionally, the device has identical indications to the predicate devices and the labeling of the device is consistent both with FDA's guidance as well as current medical practice.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 17 2003

Artimplant AB
c/o Mr. Russell P. Pagano, Ph.D.
Vice President
M Squared Associates, Inc.
719 A Street, NE
Washington, D.C. 20002

Re: K032160
Trade/Device Name: Artimplant AB, Artelon™ Surgical Suture
Regulation Number: 21 CFR 878.5020
Regulation Name: Nonabsorbable polymide surgical suture
Regulatory Class: II
Product Code: GAR
Dated: October 21, 2003
Received: October 22, 2003

Dear Dr. Pagano:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

B. INDICATIONS FOR USE

510(k) Number: to be Assigned K032160

Device Name: Artimplant AB, Artelon™ Surgical Suture

Indications for Use:

The Artelon™ Surgical Suture is intended for use in general soft tissue approximation and/or ligation.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over the Counter Use _____
(Per 21 CFR 801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032160